

## REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this amendment, claims 1-4, 6, 7, 10, 12, 13, 15-17 and 19-20 will be pending the present application. Claims 5, 14, and 18 are cancelled by this amendment, and claims 8, 9, and 11 were previously cancelled.

Claims 1-7 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,054,207 to Lazure et al. in view of the Blass et al. Article, the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, U.S. Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al. In addition, claims 12-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Blass in view of Stevens et al. (1999), Stevens et al. (1997), and Frank, in further view of Lazure, Bexkers and Hendricks. Applicant respectfully traverses these rejections for the reasons presented below.

Independent claim 1, recites an individual packaged solution for use in conjunction with a planned medical procedure on a neonatal infant. The packaged solution includes a cup-shaped container that is not attached to any other container and having a cavity defined therein opening to a mouth. A volume of a solution comprising sucrose and water is disposed within the cavity. The solution comprises about 10% to about 50% sucrose, with a remainder of the solution comprising water. A cover is disposed over the mouth and seals the solution within the cavity. The cover is defined by a material that is less rigid than a material defining the cup-shaped container, so that the cover can be incrementally removed from the container. The solution and an interior of the container are in an aseptic state. Applicant respectfully submits that the cited references do not teach or suggest such a packaged solution.

The Examiner identifies the following features as being known in the art:

- 1) Providing a single-serve cup-shaped container to contain a medicine or food in an aseptic fashion. See Lazure et al., Beckers, and Hendricks et al.; and

- 2) Administering sucrose to a neonate to relieve pain. See Franck, Stevens et al. (1999), Blass et al., and Stevens (1997)).

The Examiner infers from these two known ideas that one of ordinary skill in the art would be to produce the invention recited in independent claims 1, 12, and 17. Applicant respectfully disagrees. Applicant submits that these teachings are not sufficient to render the claimed invention obvious, because the mere fact that medicine can be placed in containers does not suggest doing so. The applicant respectfully reminds the Examiner of the danger of using hindsight to reconstruct the present application from the prior art.

Knowing the result to be achieved based on the present application, the Examiner is not permitted to pick and choose from these teachings the manner in which they need to be assembled to achieve the present invention. That is, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992)(quoting *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)).

The invention that was made does not make itself obvious; that suggestion or teaching must come from the prior art. See, e.g., *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988)(it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so); *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)( it is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor); *Fromson v. Advance Offset Plate, Inc.*, 225 U.S.P.Q. 26, 31 (Fed. Cir. 1985)(the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

For example, one of ordinary skill in the art, knowing that sucrose can be administered to alleviate pain in a neonate, may be motivated to administer the sucrose in a

manner quite different from that of the present invention. For example, one of ordinary skill in the art may provide the sucrose to a patient via a syringe, where the sucrose is drawn into the syringe from a large container of sucrose. In fact, this was the conventional technique used to provide a sucrose solution to a patient prior to the present invention.

It should be noted that there are good reasons why one skilled in the art would not want to provide the sucrose in the individual cup-shaped containers of the present invention. For example, there are extra packaging costs associated with providing individual packages of sucrose, rather than providing a bulk quantity of sucrose. Second, the use of individual cup-shaped containers may present an inventory control challenge not present if the caregiver mixes the sucrose solution only as needed. Third, sucrose solutions mixed as needed, may be perceived as being "fresher" than that provided by individual cup-shaped containers pre-mixed delivered to caregiver where it is stored until needed. For these reasons, the Examiner's conclusion as to the obviousness of the present invention fails to appreciate the practical considerations that teach against the combination of references proposed by the Examiner.

Amended independent claims 12 and 17 are patentably distinguishable over the cited references for the reasons presented above, because claims 12 and 17 recite many features of the packaged solution that is not believed to be obvious based on the cited references. In addition, claims 12 and 17 are patentably distinguishable over the cited references based on their own merits. For example, independent claims 12 and 17 recite discarding any residual solution contained within the opened, individual, single-use container after the planned medical procedure.

The Examiner contends that discarding any residual amount of medication is obvious because it is well known to discard residual material contained in single serving container. Applicant notes that a conventional medicine is provided as a single dosage. The patient is expected to take the entire dosage. The present invention does not recite providing a single dose. That is, in the present invention, the patient is provided, by means of the cup-shaped container, more than enough sucrose is needed to achieve the medical treatment, and the rest is discarded. This is quite dissimilar from a conventional medicine administration procedure in

which the entire dosage is provided in the container and there should be no medicine to discard. It is the intention of the present invention that residual sucrose should be discarded. The Examiner's suggestion that unused medicine is discarded is based on a hypothetical assumption that may not occur.

Independent claims 12 and 17 further recite providing a pacifier having a first end and a second end, and administering a selected volume dose of the solution orally to the neonatal infant by dipping the first end of the pacifier into the solution, and thereafter inserting the first end of the pacifier into a mouth of a patient. Applicant respectfully submits that the cited references do not teach or suggest using a pacifier, dipped in the sucrose solution stored in the single-use cup-shaped container, to administer the sucrose to a patient.

For the reasons presented above, applicant respectfully submits that independent claims 1, 12, and 17 are not rendered obvious by the cited references. In addition, claims 2-4, 6, 7, 10, 12, 13, 15, 16, 19, and 20 are also not rendered obvious due to their dependency from independent claims 1, 12, and 17. Claims 5, 14, and 18 have been cancelled, thereby rendering their rejection moot. Accordingly, applicant respectfully requests that the above rejections of claim 1-7, 10, and 12-20 be withdrawn.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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